

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 1-14 are pending in the application, with claims 1, 7-9, 11 and 13 being the independent claims. New claim 14 is sought to be added.

Claim 1 was amended to place a period at the end of the claim. Claims 7-9, 11 and 13 were amended to place them in independent form. Claim 10 was amended to correct a typographical error. Claim 14 was added to further specify the uses for the pharmaceutical composition. Support for new claim 14 can be found at, e.g., page 8, line 22, through page 10, line 12. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objection to the Claims

Claim 1 was objected to because a period was not placed at the end of the claim. Claim 1 has been appropriately amended.

Claims 7-9, 11 and 13 were objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claims 7-9, 11 and 13 have been amended accordingly.

It is respectfully requested that the objections to the claims be withdrawn.

Rejections under 35 U.S.C. § 112

Claims 11-13 were rejected under 35 U.S.C. § 112, first paragraph, because the specification is allegedly not enabling for preventing obesity, depression, Parkinson's disease, insulin-independent diabetes mellitus or epilepsy. The phrase "or preventing" has been deleted from claims 11-13.

Claims 11 and 13 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Examiner stated that the exact meaning of the term "related disorders" is unclear. The phrase "related disorders" has been deleted from claims 11 and 13.

It is respectfully requested that the rejections under 35 U.S.C. § 112 be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-4 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by BR 2001005486. Applicants respectfully traverse this rejection.

In order for a claim to be anticipated, each and every element of the claim must be disclosed in the cited document. BR 2001005486 does not teach sibutramine hydrogen sulfate as recited in claim 1 of the present application. The original Portuguese language (Brazilian) title of the present invention is "Novo composto farmacêutico, seus processos de obtenção e composições farmacêuticas contendo o mesmo," which means "novel pharmaceutical compound, the method for preparing it, and the pharmaceutical composition comprising the same." Thus, the original title never disclosed sibutramine hydrogen sulfate. Further evidence of this translation is found in the corresponding

Delphion search result for BR 2001005486 submitted herewith, the title of which in English is "Process is for obtaining sulphate of 1-(4-chlorophenyl)-N,N-dimethyl-alpha-(2-methylpropyl)-cyclobutanomethamine and its isomers." (Emphasis added). Thus, the compound disclosed in BR 2001005486 is sibutramine sulfate.

The cited original Portuguese language (Brazilian) abstract also mentions that "A presente invenção referente ao sulfato de 1-(4-clorofenil)-N,N-dimetil-(2-metilpropil)-ciclobutanometanamina e seus isômeros, a seus processos de fabricação e composições farmacêuticas, sendo esta uma substância com características higroscópicas reduzidas destinada a fabricação de produtos farmacêuticos," (emphasis added), which indicates the presence of sibutramine sulfate, not sibutramine hydrogen sulfate.

Moreover, the cited abstract for BR 2001005486 also discloses that sibutramine sulfate is made of two molecules of sibutramine and one molecule of sulfuric acid. See, e.g., lines 28-29 of the abstract, labeled "CN", which indicates sibutramine is in a 2:1 ratio with sulfate. Accordingly, the compound of the cited reference is sibutramine sulfate, not sibutramine hydrogen sulfate.

The compound claimed in claims 1-4 of the present application is sibutramine hydrogen sulfate. BR 2001005486 does not teach sibutramine hydrogen sulfate. Thus, claim 1 is not anticipated by BR 2001005486. Because BR 2001005486 does not teach the compound claimed in claim 1, the X-ray diffraction data in claims 2-4 are not an inherent property of the sibutramine sulfate disclosed in BR 2001005486. Thus, claims 2-4 are not anticipated by BR 2001005486.

It is respectfully requested that the rejections under 35 U.S.C. § 102(b) be withdrawn.

Rejections under 35 U.S.C. § 103

Claims 7 and 10 were rejected under 35 U.S.C. § 102(a) as allegedly being unpatentable over BR 2001005486. Applicants respectfully traverse this rejection.

The Examiner stated that BR 2001005486 teaches the sulfate salt of sibutramine. The Examiner further stated that one of ordinary skill in the art at the time of the invention would have immediately recognized, given the prior art acid addition salt, that an acid addition salt is routinely formed by adding an acid to an amine.

As discussed above, BR 2001005486 teaches sibutramine sulfate, not sibutramine hydrogen sulfate as claimed in the present application. Moreover, BR 2001005486 does not teach making sibutramine hydrogen sulfate by reacting sibutramine with sulfuric acid. Thus, BR 2001005486 in view of the knowledge of one of ordinary skill in the art does not render obvious the claimed method of making sibutramine hydrogen sulfate. Accordingly, claims 7 and 10 are not obvious in view of BR 2001005486.

Claims 1, 5, 8 and 10 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over GB 2184122 (CAPLUS abstract) and Applicants' admission in the specification. Applicants respectfully traverse this rejection.

The Examiner has the initial burden of establishing a *prima facie* case of obviousness. The Examiner stated that one of ordinary skill in the art at the time of the invention would have been motivated to search for further acid addition salts of sibutramine given the known handling difficulties of the Cl salt. The Examiner also stated that given the art's preference for the Cl salt, one of ordinary skill would have been motivated to search for acid addition salts among the halogen acid addition salts.

Finally, the Examiner stated that bromine is the next logical choice to try and that there is a reasonable expectation of success given the success of Cl salts. The Examiner has not provided any evidence to support his position.

As stated in the specification at page 2, lines 19-22, the chloride salt of sibutramine is known to be difficult to handle due to its hygroscopic nature. Accordingly, a person of ordinary skill in the art would have had a reasonable expectation that the bromine salt of sibutramine also has hygroscopic nature and will thus have similar difficulties in handling. Thus, a person of ordinary skill in the art would not have had a reason to try the bromine salt of sibutramine. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness and the bromine salt of sibutramine is not obvious in view of GB 2184122.

In view of the above arguments, it is respectfully requested that the rejections under 35 U.S.C. § 103(a) be withdrawn.

Allowable Claims

The Examiner has indicated that claims 6 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Judith U. Dim Reg. No. 40,679
for Danielle L. Letting
Agent for Applicants
Registration No. 56,971

Date: January 4, 2008

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600
762847_1.DOC